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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,575	03/18/2004	Joyce J. Evans	0170.03	4131
25712	7590	08/26/2005	EXAMINER	
USDA-ARS-OFFICE OF TECHNOLOGY TRANSFER NATIONAL CTR FOR AGRICULTURAL UTILIZATION RESEARCH 1815 N. UNIVERSITY STREET PEORIA, IL 61604			MINNIFIELD, NITA M	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/807,575	EVANS ET AL.
	Examiner N. M. Minnifield	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 10, 19 and 20 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-9 and 11-18 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 10, 19 and 20 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 3/18/04 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892) *4 pag*
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/6/04. *4 pag*

- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 11-18, drawn to a composition and method of using the composition, classified in class 424, subclass 184.1.
- II. Claim 10, drawn to biologically pure culture, classified in class 424, subclass 93.44.
- III. Claims 19 and 20, drawn to a method of producing a vaccine, classified in class 424, subclass 237.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product. An entirely different vaccine composition comprising a materially different bacterial microorganism can be made to treat a different bacterial infection.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product, for example an *E. coli* culture.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Randall Deck, 34078 on August 17, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9 and 11-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10, 19 and 20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

3. The disclosure is objected to because of the following informalities: the figure descriptions are not understood. For example, it is not clear what group is of the symbols represents in figure 2. Applicants should ensure that the figure descriptions and the actual figures and the symbols used are all the same and clearly distinguished. Appropriate correction is required.

4. Claims 5-9, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is vague and indefinite in the recitation of "substantially free"; what are the metes and bounds of this phrase? Claims 6-9, 17 and 18 are vague and indefinite in the recitation of "molecular weight greater than about 1 kDa". How was this molecular weight determined?

5. Claims 3 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter, which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 3 recites a specific deposited *S. agalactiae* with a deposit accession number of NRRL B-30608 and NRRL B-30607. The specification indicates that the “Beta hemolytic, encapsulated *S. agalactiae* brain isolates (ARS-KU-3 B and ARS-KU-11 B) were deposited on July 17, 2002, under the provisions of the Budapest Treaty in the Agricultural Research Service Culture Collection located at 1815 North University Street, Peoria, IL 61604, and have been assigned Deposit Accession No.’s NRRL 8-30608 and NRRL 8-30607, respectively.” (paragraph [0018]) It is apparent that these cultures are required to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, See 37 C.F.R. 1.802. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposits have not been made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature,

stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of the application, access to the deposits will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- © the deposits will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

It appears that Applicants may have already deposited the cultures, however the information is not complete. The deposit information as required by the Budapest Treaty has not been made. In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent

Art Unit: 1645

in U.S. patent applications. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: It was not executed in accordance with either 37 CFR 1.66 or 1.68. There is no date along with the signature on the oath.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a

background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 2, 4 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Norcross et al (4425330).

Norcross et al discloses a composition comprising inactivated *S. agalactiae* (abstract; col. 6, l. 59-68; col. 11; col. 21; Table 12; col. 31). The prior art anticipates the claimed invention.

Since the Patent Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art

reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

12. Claims 1, 2, 4, 6-9, 11-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norcross et al (4425330) taken with Evans et al (J. Fish Diseases, 2002, 25:505-513).

Norcross et al discloses a composition comprising inactivated *S. agalactiae* (abstract; col. 6, l. 59-68; col. 11; col. 21; Table 12; col. 31). Norcross et al teaches the claimed invention except for a method of protecting fish against infection by *S. agalactiae*.

However, Evans et al teaches that *S. agalactiae* were isolated from seabream, mullet and tilapia and that virulent *S. agalactiae* is a bacterial pathogen responsible for epizootic. Evans et al teaches *S. agalactiae* is one of the streptococcal species most frequently associated with disease and has been isolated from both warm-blooded terrestrial and cold-blooded aquatic animals indicating a broad host range. It is primarily isolated from human and bovine sources, causing neonatal meningitis infections and mastitis, respectively. Occasional infections in mice, cats, dogs, hamsters, camels, frogs and fishes have been reported.” (p. 505, col. 1; see also p. 506, col. 1) *S. agalactiae* has also bee isolated from freshwater golden shiners, wild gulf menhaden, hardhead sea catfish, striped mullet, Atlantic croaker, spot, stingray, silver weakfish, bullminnows, striped bass, bluefish, grey weakfish, tilapia hybrids and grey mullet (p. 506, col. 1). Experimental *S. agalactiae*

infection has been achieved in various fish species by differing routes of infection such as cohabitation, immersion and intraperitoneal (i.p.) and intra-muscular (i.m.) injections (p. 506, col. 1; p. 511, col. 2). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer to a fish the composition taught by Norcross et al that comprises an inactivated (killed) *S. agalactiae* for the purpose of protecting the fish against infection caused by *S. agalactiae* since Evans et al teach that *S. agalactiae* is a pathogen that infects fish. Evans et al teaches the numerous fishes as set forth in claims 12 and 13 as well as the methods of administration set forth in claim 14. The claimed invention is *prima facie* obvious in view of the combined teachings of Norcross et al taken with Evans et al, absent any convincing evidence to the contrary.

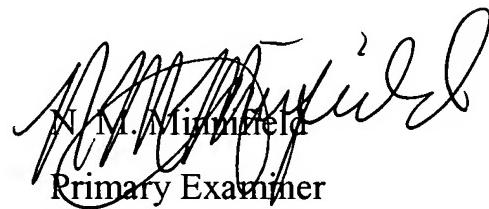
13. No claims are allowed.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



N. M. Minnfield
Primary Examiner

Art Unit 1645

NMM

August 21, 2005